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V. 510(k) Summary

This 510(k) summary is submitted in accordance to the requirements of 21 CFR 807.92.

The assigned 510(k) number is: _____

General Information

Criteria	Information
Trade Name	MobCardio System
Model Name	MHC2011.1.0
Common Name	Electrocardiography
Classification	Class II
510(k) Submitter	MobHealth Corporation 5227 Village Circle Dr. Temple City, CA 91780
Contact Person	Patricia Lin, Director of Technology Marketing patricial@mobhealth.com
Date Prepared	May 12th, 2011

Substantially Equivalent Devices

Manufacturer	Substantially Equivalent Device	510(k)
Kardiosis Ltd.	ARS-EKG 12K Electrocardiography System	K914206
ET Medical Devices Spa	Cardioline AR600	K051534
Midmark Diagnostic Group	Midmark IQecg	K103640

Predicate Device Comparison Summary:

The MobCardio System has in many instances, identical or nearly identical technological characteristics to the substantially equivalent devices. See device comparison table below:

Device name	ARS-EKG 12K ECG System (K914206)	Cardioline AR 600 (K051534)	Midmark IQecg (K103640)	MobCardio System
Intended use	Acquisition and display of resting 12-lead ECG; no interpretation	Acquisition, display, and interpretation of resting 12-lead ECG	Acquisition, display, and interpretation of resting 12-lead ECG	Acquisition and display of resting 12-lead ECG; no interpretation
Indications for use	Prescription use by trained physicians and/or medical personnel only	Prescription use by trained physicians and/or medical personnel only	Prescription use by trained physicians and/or medical personnel only	Prescription use by trained physicians and/or medical personnel only
Target population	Adult	For non interpretive applications, no limitations to age, sex and race	Adult and pediatric	Adult

Device name	ARS-EKG 12K ECG System (K914206)	Cardioline AR 600 (K051534)	Midmark IQecg (K103640)	MobCardio System
Anatomical sites	External surface of chest and limbs	External surface of chest and limbs	External surface of chest and limbs	External surface of chest and limbs
Where used	Healthcare facilities/Hospitals	Healthcare facilities/Hospitals	Healthcare facilities/Hospitals	Healthcare facilities/Hospitals
Energy used and/or delivered	PC powered (PC EKG add-on card)	AC Main/External battery power	External battery power/PC-USB powered	USB powered/AC adapter and rechargeable battery for medical grade laptop
Design	EKG data acquisition module (PC-ISA) with software for data processing, display, storage, and print	EKG data acquisition, storage and print device (infrared serial) with software for interpretation, display, storage, and print	EKG data acquisition module (USB/RS232) with software for data processing, interpretation, display, storage, and print	EKG data acquisition module (PC-USB) AND medical grade PC with software for data processing, display, storage, and print
Standards met	• IEC 60601-1:1990 • AAMI EC11:1982 • AAMI ES1:1985	• IEC 60601-1:2006 • IEC 60601-1-2:1993 • IEC 60601-2-25:1995 • IEC 60601-2-51:2003	• IEC 60601-1:2006 • IEC 60601-1-2:2007 • IEC 60601-2-25:1999 • AAMI EC11:2007	• IEC 60601-1:2006 • IEC 60601-1-2:2007 • IEC 60601-2-25:1999 • IEC 60601-2-51:2005 • AAMI EC11:2007
Bio-compatibility	Not applicable	Not applicable	Not applicable	Not applicable
Sterility	Not applicable	Not applicable	Not applicable	Not applicable
Electrical/Compatibility w/environment & other devices	Passed EMC test - met IEC 60601-1, AAMI ES11 and ES1 requirements	Passed EMC and LVD tests - met IEC 60601-1, IEC 60601-1-2, IEC 60601-2-25 requirements	Passed EMC and LVD tests - met IEC 60601-1, IEC 60601-1-2, IEC 60601-2-25 requirements	Passed EMC and LVD tests - met IEC 60601-1, IEC 60601-1-2, IEC 60601-2-25 requirements
Mechanical safety	ECG amplifiers (e.g. input protection against defibrillation shocks, type BF applied part)	ECG amplifiers (e.g. input protection against defibrillation shocks, type CF applied part)	ECG amplifiers (e.g. input protection against defibrillation shocks, type CF applied part)	ECG amplifiers (e.g. input protection against defibrillation shocks, type BF applied part)

Summary of Substantial Equivalence

After comparing the indications for use, technology, and performance specifications of the listed predicate devices and the MobCardio System, we have concluded that the proposed device does not raise any new safety or effectiveness issues and is substantially equivalent to the listed predicate devices.

Device Description

The MobCardio System is comprised of an EKG acquisition module (connected via a PC-USB cable), a 12-lead EKG patient cable, a medical grade laptop, and the user software. The device is used to collect, transmit, and display resting 12-lead EKG data using FDA cleared disposable EKG electrodes and manufacturer supplied 12-lead EKG patient cable.

The user software is pre-installed for the user and provides necessary menus and user interfaces for displaying and printing the acquired 12-lead EKG data.

The MobCardio System is compatible with any desktop or notebook computer with a suitable USB port (1.0 or above) and Windows operating system. While we offer the EKG acquisition module and the medical grade laptop as a system, the user has the option to use a personal computer that fits the requirements listed in the device user manual. Without being connected to a computer, the EKG data acquired will not be displayed and no EKG prints out can be obtained.

Indications for Use

The MobCardio System is intended to be used by trained operators under the direct supervision of a licensed healthcare practitioner on adult populations. The device is designed to collect, transmit, and display resting 12 lead EKG data. The clinical and diagnostic evaluation of acquired EKG signals should be made by a physician, who has experience or is specialized in Cardiology. No clinical interpretation of EKG is provided.

Functional and Safety Testing

Device components underwent safety and bench testing on both hardware and software and demonstrated acceptable functional and performance results. No safety and effectiveness issues were raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

NOV 17 2011

MobHealth Corporation
c/o Mr. Mark Job
Reviewer
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 53313

Re: K113234
Trade/Device Name: MobCardio System
Regulatory Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: II (two)
Product Code: DPS
Dated: November 1, 2011
Received: November 2, 2011

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K113234

IV. Indications for Use Statement

510(k) Number (if known): K113234

Device Name: MobCardio System

Indications For Use:

The MobCardio System is intended to be used by trained operators under the direct supervision of a licensed healthcare practitioner on adult populations. The device is designed to collect, transmit, and display resting 12 lead EKG data. The clinical and diagnostic evaluation of acquired EKG signals should be made by a physician, who has experience or is specialized in Cardiology. No clinical interpretation of EKG is provided.

Prescription Use __X__	**AND/OR**	**Over the Counter Use ____**
(21 CFR Part 801 Subpart D)		(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K113234